

EXHIBIT D

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EXPERT REPORT OF ROBERT L. HILL

In re National Prescription Opiate Litigation MDL No. 2804
Track One

May 31, 2019

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clearly is to detect any problem or issue that indicates an order may not be valid or legitimate. The review and analysis of irregular orders are completed expeditiously; and while sales productivity, customer store and patient satisfaction are paramount, the foundation of the CVS SOM is ensuring the legitimacy of these transactions.”⁷⁷

53. This system was designed, evaluated, or assisted by three former high-ranking DEA officials from the Office of Diversion Control.⁷⁸ The selection of these individuals shows CVS’s commitment to its suspicious order monitoring program.

c. Early 2014 – End of 2014

54. In early 2014, CVS replaced the Buzzeo system with a new computerized system to assist in identifying potentially suspicious orders. Like the Buzzeo system, this system operated in conjunction with controls discussed above in Section V.E.2.a. Even though this system has been in operation continuously through the present, CVS stopped distributing HCPs after September 2014. I travelled to CVS corporate headquarters in Woonsocket, Rhode Island to see the system in operation. While there, I sat with one of the analysts (Megan Matos) and the group supervisor (Annette Lamoureux) and observed their work in real-time.

55. The new system is based on a set of computerized tests that identifies orders for review. Some of the tests are based on size, some are based on frequency, and some are based on ordering pattern. The tests are run overnight against every order placed by a CVS pharmacy the preceding day, and the system identifies orders for review based on one or more of the tests. Every order that is identified is then held and placed in a queue for review.

56. Beginning in the early morning, CVS analysts begin their reviews by selecting an order from the queue. The analyst opens a file, which shows basic information about the order for review, such as the drug that was ordered, how much was ordered, the pharmacy it was ordered from, and the distribution center that would fill the order. The computer interface allows the analyst to link to more specific information. For example, the analyst can see information

⁷⁷ CVS-MDLT1-000125136 (April 6, 2012 DCAG Report).

⁷⁸ This system covered all of the CVS distribution centers that were registered to distribute Schedule III-V controlled substances. Other than the 2015 LOA issued to the Indianapolis distribution center discussed above, DEA never took any action against CVS based on this system. CVS-MDLT1-000123069 (CVS Official Government Agency Visits); Conversation with Pam Hinkle, Senior Manager of Logistics Compliance.

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related to the relevant tests, the pharmacy, the order, the patient, the prescriber, cocktail information, and the method of payment. The analyst can supplement his or her review through additional information, such as a map showing what is in the vicinity of the pharmacy, a comparison of the amount of the drug ordered and the amount dispensed, the balance on hand for the particular drug at the pharmacy, and the distance the patient travelled. All of this information is accessible through each analyst's computer. When deemed necessary, an analyst may also call the pharmacy to ask any questions raised by his or her review.

57. Based on an analyst's review of this information, the analyst decides whether to clear the order or not. If the analyst is unable to resolve any questions about the order, the order continues to be held and is elevated for further review. The order is then either: (1) cleared as not suspicious; or (2) identified as suspicious, not shipped and reported to DEA.

58. In my opinion, this system complied with 21 C.F.R. § 1301.74(b) and was reasonable.

F. It is Reasonable that CVS Did Not Discover Any Suspicious Orders Placed by Pharmacies in Summit and Cuyahoga Counties.

59. DEA regulations require a system to disclose and report, when discovered, suspicious orders. However, this does not mean a customer will place a suspicious order.⁷⁹ If no suspicious orders are placed, there are none for the distributor to discover or report. Based on the circumstances here, it is reasonable in my opinion that CVS did not discover any suspicious orders placed by any of the CVS pharmacies in Cuyahoga and Summit counties and therefore did not report any.

60. First, CVS distributed only to CVS pharmacies.⁸⁰ It did not distribute to known sources of diversion, such as rogue pain clinics, rogue internet pharmacies, or dispensing practitioners. CVS therefore did not receive orders from these types of customers.

61. Second, CVS did not distribute any of the controlled substances that were considered to have the highest potential for abuse of any prescription drugs (Schedule II).⁸¹ It did not

⁷⁹ 21 C.F.R. § 1301.74(b).

⁸⁰ Deposition of Mark Vernazza. p. 56:10-13 (the two CVS defendants "only distributed controlled substances to CVS pharmacies, to the best of my corporate knowledge."); Expert Report of Sonya Kwon, pp. 7-9.

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distribute drugs like fentanyl, hydromorphone oxycodone, or oxymorphone. Of the controlled substances relevant to this lawsuit, CVS only distributed HCPs, which were Schedule III controlled substances until October 6, 2014, and voluntarily stopped distributing them when DEA reclassified them to Schedule II.⁸² CVS only distributed about 2.3% of Morphine Milligram Equivalence (“MME”) into Cuyahoga County and 2.0% of MMEs into Summit County from 2006 through CVS’s last shipment of HCPs in September of 2014.⁸³

62. Third, as required by ARCOS, CVS reported to DEA all shipments of hydrocodone combination products to its pharmacies in Cuyahoga and Summit counties.⁸⁴ DEA never indicated to CVS that any of the orders placed by its pharmacies in Cuyahoga and Summit counties should have been discovered as suspicious and never brought any orders to show cause, immediate suspension orders, or civil or criminal actions based on these shipments.⁸⁵ The Ohio Board of Pharmacy also regulated the distribution of controlled substances within the state of Ohio⁸⁶, and also required distributors to report all shipments of HCPs.⁸⁷ Like DEA, the Ohio Board of Pharmacy never indicated to CVS that any of the orders placed by its pharmacies in

⁸¹ Deposition of Mark Vernazza. p. 56:2-9 (“Both of the CVS entities named as defendants in this case are distributors of controlled substances. They are now, and have always been, only distributors of Schedule III through V controlled substances, and have never been distributors of Schedule II controlled substances.”); 21 U.S.C. § 812(b)(2) (defining Schedule II controlled substances as having “a high potential for abuse” and “a currently accepted medical use[.]”); Expert Report of Sonya Kwon, pp. 9-11.

⁸² Expert Report of Sonya Kwon, pp. 9-11.

⁸³ Expert Report of Sonya Kwon, pp. 12-14.

⁸⁴ 21 C.F.R. § 1304.33; Expert Report of Sonya Kwon, p. 6 (stating “I compared the summaries of HCP transactions and total weight from the ARCOS and CVS distribution data described in the preceding paragraphs. I determined both datasets capture the same shipments with similar number of packages and active ingredient weights.”).

⁸⁵ Conversation with Pam Hinkle, Senior Manager of Logistics Compliance.

⁸⁶ Ohio Admin. Code 4729:9-16(H)(1)(e) (2006) (“A system of procedures shall be designed and operated to disclose orders for controlled substances and other dangerous drugs subject to abuse (i) The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs, as described in paragraph (H)(1)(e) of this rule, when discovered. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns. (ii) Reports, generated by the system as described in paragraph (H)(1)(e) of this rule, shall be furnished to the state board of pharmacy within three working days of receipt of a request from the board. The reports shall include the name and address of the purchaser, date of purchases, product trade name, national drug code (NDC) number, size of package, and quantity purchased.”).

⁸⁷ Ohio Admin. Code 4729-37-03(B) (2006); Ohio Admin. Code 4729-37-03(C) (2011).

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Cuyahoga and Summit counties were suspicious and never took any action against CVS for failing to report or discover suspicious orders.⁸⁸

63. Fourth, from 2006 to 2014, neither the Ohio Board of Pharmacy nor DEA suspended or revoked the license of any of the sixty-nine CVS pharmacies in Summit or Cuyahoga counties.⁸⁹ Both the Ohio Board of Pharmacy and the DEA had the authority to conduct periodic inspections of pharmacies.⁹⁰ In my experience, the Board of Pharmacy and DEA would have inspected CVS pharmacies many times during this period. In addition, the Ohio Board of Pharmacy had access to the Ohio Automated Rx Reporting System (“OARRS”), which included data on controlled substance prescriptions filled by these pharmacies.⁹¹

64. Fifth, CVS pharmacies in Summit and Cuyahoga counties, to which CVS was distributing HCPs, were legitimate, everyday, full-service pharmacies placing orders necessary to address the full range of medical needs of their customers. This is shown by the small proportion of controlled substances to non-controlled substances distributed to its pharmacies in Summit and Cuyahoga counties.⁹² From 2006 through September 2014, “[c]ontrolled substances represent less than 8.5% of shipments, less than 6.2% of packages, and less than 13.5% of dosage units shipped to CVS pharmacies in Cuyahoga and Summit counties by CVS distribution centers and Cardinal Health combined[.]”⁹³

⁸⁸ Conversation with Pam Hinkle, Senior Manager of Logistics Compliance.

⁸⁹ Conversation with Linda Cimbron, Director of Licensing; Expert Report of Sonya Kwon, p. 7 fn.23 (“There are 69 CVS stores in the distribution data with shipments between 1/1/2006 and 9/30/2014.”).

⁹⁰ Ohio Admin. Code 4729-9-16(L)(1) (2006); 21 U.S.C. § 880.

⁹¹ Ohio Admin. Code 4729-37-03(A) (2006); Ohio Admin. Code 4729-37-03(B) (2011).

⁹² Expert Report of Sonya Kwon, pp. 16-24.

⁹³ Expert Report of Sonya Kwon, p. 21. Broken down by store during this time period, the percentage of controlled substances by number of shipments from CVS and Cardinal Health ranged from 4.8% to 12.7%; the percentage of controlled substances by number of packages shipped from CVS and Cardinal Health ranged from 3.0% to 10.7%; the percentage of controlled substances by number of dosage units shipped from CVS and Cardinal Health ranged from 6.5% to 22.5%. Expert Report of Sonya Kwon, Exhibit 14C, 15C, 16C. Joseph Rannazzisi, the former Deputy Assistant Administer, Office of Diversion Control testified that “for the most part, pharmacies generally follow a pattern of ordering for controlled substances and depending on what we have read, it could be anywhere as low as 9 percent to up to 12 or 13 percent as the average. So it is a red flag when a pharmacy is ordering, you know, 40, 50 percent of their drugs has controlled substances[.]” Joseph Rannazzisi. pp, 453:21-454:3.